REMARKS

Summary of the Office Action

Claims 1-25 and 27 are pending in the application.

Claims 1-25 and 27 have been rejected as anticipated by or obvious over Armini, U.S. Patent No. 6,183,409 ("Armini").

Applicant's Response

Applicant traverses the rejections based on Armini because that reference discloses an entirely different class of atoms that are used in an entirely different way to produce a different spectrum of radiation than those described and claimed in the present application. All of the radioactive isotopes described in Armini are created by irradiating the stents in a nuclear reactor ***prior to*** implantation within the patient's body. None "***emit[] therapeutic irradiation substantially only while being exposed to a thermal neutron irradiation***" as recited in independent claims 1, 15 and 20. Armini's preferred radio-isotopes emit beta particles or x-ray radiation, not gamma radiation. And all of the radio-isotopes described in Armini have half-lives of from two to seventy ***days***, not ***milliseconds*** as described in the present application. Armini does not anticipate or render obvious any aspect of the claimed invention.

Although applicant submits that the claims already patentably distinguish over the prior art, applicant has amended claims 1 and 15 to clarify that the stent is "configured for implantation within a patient's body" and that "***emits therapeutic irradiation substantially only while being***

exposed to a thermal neutron irradiation after implantation in the patient's body." Armini nowhere teaches nor suggests that the stents described therein should or could be irradiated with a thermal neutron flux after implantation in the patient's body to activate the precursor elements described as suitable for use in creating radioactive stents. On the contrary, Armini describes only that the stents are activated *ex vivo* by exposure within a ***nuclear reactor*** prior to implantation. See, e.g., col. 2, lines 46-53 ("...activating the ^{168}Yb atoms in a ***nuclear reactor...***"); col. 4, lines 60-63; col. 5, lines 11-12; col. 8, lines 39-46 and col. 8, lines 47-50.

That Armini relies on the use of a nuclear reactor to activate the radio-isotopes prior to implantation also necessarily means that the stents described in Armini cannot emits therapeutic irradiation substantially ***only while being exposed*** to a thermal neutron irradiation. As described in the present application, the radio-isotopes formed by the elements used in the stents of the present invention have half-lives on the order of a few milliseconds, and therefore emit therapeutic radiation ***only during the period that the stent is being irradiated in situ in the patient's body.*** Once the thermal irradiation ceases, the stent quickly returns to its non-radioactive form. See, e.g., page 9, lines 9-24 and page 10, line 16 to page 11, line 13.

By contrast, Armini's stents are irradiated in prior to implantation in a nuclear reactor. The elements identified for use in the stents of the present invention would therefore be ***useless*** in the context of Armini's stents because by the time the stent had been removed from the nuclear reactor and transported to the patient, the radio-isotopes would already have decayed to their non-radioactive states. Indeed, this is

why Armini specifies that:

> The criteria for selection of a stable precursor element that is to be neutron-activated include: having a half-life between **about two and about thirty days**, or between about two and about seventy days; having a high neutron activation cross-section; and having the resultant radioisotope **primarily emit beta particles or x-rays rather than gamma rays.**

This passage actually ***teaches away*** from use of the short half-life elements identified in the present invention, which have half-lives on the order of milliseconds and emit primarily high energy gamma radiation. See page 8, lines 7-9; page 10, line 30 to page 11, line 3 and page 11, lines 7-13.

The selection criteria set forth in Armini plainly disqualify the precursor elements identified for use in the stents of the present invention as having "unacceptably" short half-lives and the "wrong" radiation spectrum. Accordingly, in no sense can Armini be considered as anticipating or rendering obvious the disclosed invention. To the extent that Armini provides any teaching relevant to the present invention, it is that the precursor elements disclosed in the present invention would be unsuitable for a stent intended for radiation therapy.

With respect to claim 20, applicant traverses the argument in paragraph 4, bridging pages 3-4 of the Office action that states that "the steps as claimed are inherently carried out as Armini's stent being made or used." As noted above, all of the stents described in Armini are activated ***prior to implantation***. Thus, the method of using the stent in Armini does not involve "deploying the stent at a treatment site within a patient's vasculature" and then "externally irradiating the patient near the treatment site with a thermal neutron irradiation..." as recited in claim 20.

With respect to the purported rationale for substituting the precursor elements of the present invention for those in Armini set forth in paragraph 6, pages 3-4 of the Office action, applicant notes that such substitution would not have been obvious because, based on the teachings of Armini, one of ordinary skill would have expected the proposed substitution to result in an ***inoperative device*** (i.e., that would have a sufficiently long half-life to be practicable and that emitted the "wrong" type of radiation).

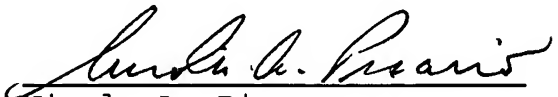
Applicant's invention, however, ***does*** solve a problem encountered with previously-known stents, including those described in Armini, by eliminating the requirement that the stent be activated prior to implantation. Applicant's stent therefore poses no risk of radiation exposure to manufacturing workers or clinical staff during implantation, and the very short half-life of the stent ensures that radiation exposure to the patient is tightly controlled. None of these benefits could be achieved without the present inventor's substantial departure from the methods and thinking of the previously known workers in the field of radioactive stents.

Accordingly, applicant submits that independent claims 1, 15 and 20 patentably distinguish over the prior art for the reasons set forth above. Applicant further submits that dependent claims 2-14, 16-19, and 21-25 and 27, which depend from independent claims 1, 15, and 20, respectively, patentably distinguish over the prior art of record for at least the same reasons as the independent claims.

CONCLUSION

In view of the foregoing, applicant respectfully submits that the application is in condition for allowance. An early and favorable action is earnestly requested.

Respectfully submitted,



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